

REMARKS

Claims 1-20 are pending. Claims 9 and 12 are currently amended. Claim 28 and 29 are new. Reconsideration of the application in view of the amendments above and remarks below is requested.

I. The Rejection of Claim 9 under 35 U.S.C. 112

Claim 9 stands rejected as indefinite for being vague and indefinite. Claim 9 has been amended to make it clear. Reconsideration is urged.

II. The Rejection of Claims 1-20 under 35 U.S.C. 102(b)/103

Claims 1-20 stand rejected under 35 U.S.C. 102/103 as allegedly anticipated or obvious in light of U.S. Patent No. 5,858,952 (hereinafter referred to simply as "Izawa"). This rejection is respectfully traversed.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Independent claims 1 and 19 require, *inter alia*, a core matrix and one or more coatings, wherein the core matrix includes: an active compound; a synthetic polymer in an amount of 0.1 to 10 % by weight of the core matrix; and antioxidant or reducing agent in an amount of 0.2 to 5 % by weight of the core matrix. In other words, a core matrix must include three constituents (two of which are in specified amounts), and the core matrix must have one or more coatings. Nowhere does Izawa disclose such a core matrix with a coating. Applicants note that matrix is specifically defined in the specification to refer to the mixture which comprises the active compound. Further, core matrix is defined to either make up the entire homogenous core of the granule or make up the mixture which is applied to a preformed inert core. Nowhere does Izawa disclose the claimed core matrix including the three constituents (two of which are in specified amounts). More specifically, nowhere does Izawa describe a composition having a synthetic polymer in an amount of 0.1 to 10 % by weight of the core matrix and antioxidant or reducing agent in an amount of 0.2 to 5 % by weight of the core matrix. To allege anticipation, the Examiner has directed applicant's attention to Col. 4, lines 33-47 to support the statement that "core further contains film-forming polymers, such

as polyvinyl alcohol, polyvinyl pyrrolidone and starch..." Applicants respectfully disagree with the Examiner. The materials described by the Examiner are specifically described in Izawa as "Materials used for coating the enzyme-containing granulated product" Thus, Izawa specifically distinguishes these polymers for use in the coating and not a core matrix in accordance with the Applicants' disclosure. Accordingly, it is respectfully submitted that Izawa does not show each and every element of independent claims 1 and 19, and the independent claims are not anticipated. Reconsideration is urged.

The Examiner has indicated that Izawa includes magnesium sulfate. Applicants respectfully disagree that this salt is specifically disclosed in Izawa and request that the Examiner specifically point out where this salt is disclosed. Applicants respectfully submit that this salt is not disclosed and that claims 12, 13 and new claim 29 are not anticipated to the extent that they refer to magnesium sulfate. Reconsideration is urged.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir.1991).

Independent claims 1 and 19 require, *inter alia*, a granule including a core matrix and one or more coatings, wherein the core matrix includes: an active compound; a synthetic polymer in an amount of 0.1 to 10 % by weight of the core matrix; and antioxidant or reducing agent in an amount of 0.2 to 5 % by weight of the core matrix. As described above, Izawa fails to describe the claimed core matrix and one or more coatings, wherein the core matrix includes: an active compound; a synthetic polymer in an amount of 0.1 to 10 % by weight of the core matrix; and antioxidant or reducing agent in an amount of 0.2 to 5 % by weight of the core matrix. Accordingly, Izawa fails to teach each and every element of independent claims 1 and 19 and the claimed invention is not obvious. Reconsideration is urged.

Moreover, the motivation offered by the Examiner to combine coatings materials of Izawa

with the core material of Izawa is that the single reference allegedly teaches all of the claimed ingredients within the same proportions for the same utility. Applicants respectfully traverse the Examiner's position and submit that this is improper for the following reasons.

First, although Izawa does mention, *inter alia*, certain polymers for use in a coating, Izawa is devoid of any indication of using these polymers in a core matrix in the requisite amount. Thus, Izawa provides no direction as to which of the many possible choices of amounts are likely to be successful. Obvious-to-try rational is improper where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful. Obvious-to-try occurs where the prior art gives only general guidance as to the particular form of the claimed invention or how to achieve it. Accordingly, the Examiner is using improper obvious to try rational and independent claims 1 and 19 are not obvious.

Second, even assuming that the Examiner is correct in that coating materials of Izawa could be used with the core materials of Izawa (which Applicants do not concede would be proper), the mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990). See also, *In re Jones*, where the Court found there was no suggestion to combine the references to arrive at the claimed invention. Note, as the prior art does not even teach using polymers in a core matrix in the requisite amounts. Accordingly, independent claims 1 and 19 are not obvious and reconsideration is urged.

III. The Rejection of Claims 1-20 under 35 U.S.C. 102(e)/103

Claims 1-20 stand rejected under 35 U.S.C. 102(e)/103 as allegedly anticipated or obvious in light of U.S. Patent No. 7,070,820 (hereinafter referred to simply as "Simonsen"). This rejection is respectfully traversed.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Independent claims 1 and 19 require, *inter alia*, a core matrix and one or more coatings, wherein the core matrix includes: an active compound; a synthetic polymer in an amount of 0.1 to 10 % by weight of the core matrix; and antioxidant or reducing agent in an amount of 0.2 to 5 % by weight of the core matrix. In other words, a core matrix must include a specific combination of three constituents (two of which are in specified amounts), and the core matrix must have one or more coatings. Applicants note that matrix is specifically defined in the specification to refer to the mixture which comprises the active compound. Further, core matrix is defined to either make up the entire homogenous core of the granule or make up the mixture which is applied to a preformed inert core. Nowhere does Simonsen disclose the claimed core matrix including the combination of three constituents (two of which are in specified amounts). More specifically, nowhere does Simonsen describe a combination of synthetic polymer in an amount of 0.1 to 10 % by weight of the core matrix and antioxidant or reducing agent in an amount of 0.2 to 5 % by weight of the core matrix. To allege anticipation, the Examiner has directed applicant's attention to Col. 6, lines 36- Col. 7, line 65, and Col. 10, lines 1-7 to support the statement that "core also contains polymers, such as polyvinyl pyrrolidone, polyvinyl alcohol, and starch". Applicants respectfully disagree with the Examiner. The materials described by the Examiner are specifically described in Simonsen under the section "Other Coating Materials". Thus, Simonsen specifically distinguishes these polymers for use in the coating and not a core matrix in accordance with the Applicants' disclosure. Accordingly, it is respectfully submitted that Simonsen does not show each and every element of independent claims 1 and 19, and the independent claims are not anticipated. Reconsideration is urged.

The Examiner has indicated that Simonsen includes magnesium sulfate. (Please note that "MnSO₄" in Col. 7, line 14 refers to manganese (Mn) and not magnesium (Mg)). Applicants respectfully disagree that this salt is specifically disclosed in Simonsen and request that the Examiner specifically point out where the use of this salt is disclosed. Applicants respectfully submit that this salt is not disclosed and that claims 12, 13 and new claim 29 are not anticipated to the extent that they refer to magnesium sulfate. Reconsideration is urged.

Moreover, the motivation offered by the Examiner to combine coatings materials of Simonsen with the core material of Simonsen is that the reference allegedly teaches all of the claimed ingredients within the same proportions for the same utility. Applicants respectfully traverse the Examiner's position and submit that this is improper for the following reasons.

First, although Simonsen does mention, *inter alia*, certain polymers for use in a coating, Simonsen is devoid of any indication of using the claimed synthetic polymers in a core matrix in the requisite amount. Thus, Simonsen provides no direction as to which of the many possible choices of amounts are likely to be successful. Obvious-to-try rationale is improper where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful. Obvious-to-try rationale is improper when the prior art gives only general guidance as to the particular form of the claimed invention or how to achieve it. Accordingly, the Examiner is using improper obvious to try rationale and independent claims 1 and 19 are not obvious.

Second, even assuming that the Examiner is correct in that coating materials of Simonsen could be used with the core materials of Simonsen (which Applicants do not concede would be proper), the mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir.1990). See also, *In re Jones*, where the Court found there was no suggestion to combine the references to arrive at the claimed invention. Note, as the prior art does not even teach using enzyme stabilizing agents of Simonsen in a core matrix in the requisite amounts, and there can be no desirability to combine the coating materials cited by the examiner with the claimed core materials. Accordingly, independent claims 1 and 19 are not obvious and reconsideration is urged.

IV. Conclusion

In view of the above, it is respectfully submitted that all claims are in condition for allowance. Early action to that end is respectfully requested. The Examiner is hereby invited to contact the undersigned by telephone if there are any questions concerning this amendment or application.

Respectfully submitted,

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